REMARKS

Claims 1-2 and 5-19 are now pending.

Applicants traverse the rejection of claims 1-2, 5-12, and 14-18 under 35 U.S.C. § 112, second paragraph. The Office objects to the phrase "an occult component of at least about 50% to 100% of the lesion." The Office alleges that the specification does not provide a standard for ascertaining the requisite degree of the occult component and that assessing such degree may vary from one clinician to the next. However, applicants respectfully submit that the determination of lesion components (i.e., classic or occult) is described in the present application in Example 2 in the last two paragraphs of page 41. Further, applicants respectfully submit that a skilled artisan would understand the scope of the claimed invention. Enclosed herewith is literature from the website of AMD Alliance International, which is a respected non-profit coalition of the world's leading vision and seniors' organizations focusing on age-related macular degeneration (AMD). AMD Alliance International describes predominantly classic CNV as having "a mix of both classic and occult CNV characteristics.... [wherein] the classic component makes up more than 50% of the entire lesion." Minimally classic CNV is defined as a lesion wherein "the classic component occupies less than 50% of the total lesion area and the occult component is more than 50% of the lesion." Applicants respectfully submit that the occult lesion as described analogously in the claims as comprising "an occult component of at least about 50% to 100% of the lesion." Thus, applicants respectfully submit that the components of lesions as claimed is an art-accepted definition of the components and thus, a skilled artisan would be apprised of the scope of the claimed invention. Applicants respectfully submit that the specification need not provide a standard for ascertaining the degree of occult component of at least 50-100%, but rather the claim should be analyzed by the interpretation that would be given by one possessing ordinary level of skill in the art. Please see MPEP § 2173.02. Applicants respectfully submit that the claims circumscribe a particular subject matter with a reasonable degree of clarity and particularity that would be understood by a skilled artisan as supported by AMD Alliance International's definitions. Thus, applicants respectfully request withdrawal of the indefiniteness rejection.

Applicants traverse the rejection of claims 1-2, 5-12, and 14-18 under 35 U.S.C. § 103(a) as being obvious over TAP Report 1, described on pages 4-5 of the present application. On page 1329, the TAP Report 1 states: "No statistically significant differences in visual acuity were noted when the area of classic CNV was more than 0% but less than 50% of the area of the entire lesion." Please see right column on page 1329, the paragraph entitled "Results". The table on page 5 of the TAP Report 1 supports this conclusion, namely, patients with less than 50% classic CNV which received verteporfin in comparison to placebo had roughly the same results with respect to loss of less than 15 letters after one year. The group of subjects that generated these data is the only group that can be considered mathematically to have had a lesion with an occult component of greater than 50% of the lesion as claimed. In contrast, applicants have shown that these results are not applicable to a subgroup of patients having an occult CNV lesion that had a lesion size of less than about 4-5 disc areas and/or where visual acuity was about 65 letters or less. Table 2 describes that for the group of subjects treated with verteporfin that had visual acuity of less than 65 letters (regardless of lesion size), almost a 34% differential in comparison with the placebo-treated group with respect to the percent of subjects that lost less than 15 letters. For the group of subjects that had visual acuity of 65 or more letters and a lesion size of 4 disc areas or less had a 12.5% differential in comparison to the placebo counterparts. However, surprisingly the group of subjects having a visual acuity of 65 letters or more *and* a lesion size of 4 disc areas or more fared much worse than the placebo counterparts (a -24% differential). Thus, these results show that there were indeed significant differences in a subgroup of subjects as claimed having an occult CNV lesion. As described on page 5 of the present application, there is no reason to anticipate that a differential pattern of response to PDT would result based on the parameters of the claimed visual acuity and lesion size. Without being bound by theory, one might expect subjects with larger lesions to experience a greater benefit than those with smaller lesions. However, unlike the TAP Report 1, the applicants have discovered a subpopulation of occult subjects that benefit from PDT. Thus, the TAP Report 1 does not disclose or suggest the claimed subgroup nor a reasonable expectation of success. Even if such was present, applicants have shown advantageous results.

Moreover, it is not enough that the "intended purpose is inherently achieved" as alleged in the Office Action on page 4. Relevant to the analysis are two cases, namely, *In re Baird*, 16 F3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); and *In re Jones*, 958 F2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In these cases, the Federal Circuit has made it clear that, unless the document disclosing the genus points specifically toward the species claimed, the document disclosing the genus does not render the species unpatentable thereover. The species defined in the present claims is a subgroup of patients having an occult lesion and having a particular lesion size and/or visual acuity. There is no motivation to select the claimed subgroup from the disclosure of a genus of patients having an occult lesion in the TAP Report 1. At best, this reference suggests that the treatment will not work with patients having an occult CNV lesion.

Examiner Sharareh's analysis is misplaced. Although the TAP Report 1 discloses that 305 patients had evidence of an occult CNV, 199 patients had visual acuity of less than 53 letters, and 259 had a lesion size of less than 6 disc areas, such a disclosure is insufficient to lead a skilled artisan to select the particular lesion size (less than about 4-5 disc areas) and/or visual acuity (less than about 65 letters) as claimed with a reasonable expectation that treating such a group would be successful. Applicants respectfully submit that according to MPEP § 2144.08 "The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." Thus, even if for the sake of argument, the claimed subgroup was encompassed by the TAP Report's genus such is insufficient to establish obviousness. Thus, withdrawal of this rejection is requested.

Applicant traverse the rejection of claims 1-2 and 5-19 under 35 U.S.C. § 103(a) as being unpatentable over TAP Report 1 in view of Zeimer. The arguments above are incorporated here. Zeimer does not disclose a subject having an occult CNV lesion or the step of selecting such a subject and thus does not overcome the deficiencies of The TAP Report 1 in establishing obviousness. Thus, as *prima facie* obviousness has not been established, applicants respectfully request withdrawal of this rejection.

CONCLUSION

The Office has not established that the TAP Report 1 discloses the claimed subgroup. There is no motivation to select the subgroup when the whole of the TAP Report 1 leads one away from selecting occult CNV patients for treatment. Further, applicants respectfully submit that the present application shows evidence of advantageous results that has not been considered by the Office. Further, Zeimer does not overcome the deficiencies of the TAP Report 1. Thus, *prima facie* obviousness has not been established, and even if, for the sake of argument, it was established, the advantageous results as shown in the present application must be considered.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 273012012500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 16, 2006

Respectfully submitted,

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AMD ALLIANCE AND THE CANADIAN AFFILIATES

The AMD Alliance International is a nonprofit coalition of the world's leading vision and seniors' organizations working to raise awareness of age-related macular degeneration (AMD) and understanding of available options for prevention, early detection, treatment, rehabilitation and support services. It is the only international organization that concentrates exclusively on AMD, the leading cause of 'legal blindness' and severe vision loss to people over age 50 in

the Western world. To maximize its international reach, the Alliance currently represents organizations based in Argentina, Australia, Austria, Belgium , Brazil, Canada, Finland, France, Germany, Hong Kong, India, Ireland , Israel, Italy, Netherlands, New Zealand, South Africa, Spain, Switzerland , United Kingdom and United States.

Our Mission

The AMD Alliance International strives to bring knowledge, help and hope to individuals and families around the world affected by AMD.

Our mission is accomplished through:

- Generating awareness and understanding of age-related macular degeneration;
- Promoting the importance of education, early detection, knowledge of treatment and rehabilitation options; and
- Preserving vision and improving the quality of life of individuals affected by age-related macular degeneration.

OUR CANADIAN AFFILIATES

THE CANADIAN NATIONAL INSTITUTE FOR THE BLIND (CNIB)
The Canadian National Institute for the Blind (CNIB) is the primary provider of vision loss support services to over 100,000 Canadians and houses one of the world's largest specialized libraries. A new client walks through the CNIB's doors every ten minutes of every working day. Seventy-nine per cent of CNIB's annual revenues are received from individuals, foundations and corporate donors, with the balance contributed by government.

www.cnib.ca >

AMD ALLIANCE INTERNATIONAL
The AMD Alliance International is a non-profit coalition of the world's leading vision and seniors' organizations working to raise awareness of age-related macular degeneration (AMD) and understanding of available options for prevention, early detection, treatment, rehabilitation and support services. It is the only international organization that concentrates exclusively on AMD, the leading cause of blindness and severe vision loss to people over the age of 50 in the Western world.

www.amdalliance.org >

CANADIAN OPHTHALMOLOGICAL SOCIETY (COS)
The purpose of the Canadian Ophthalmological Society (COS) is to assure the provision of optimal eye care to all Canadians by promoting excellence in ophthalmology and providing services to support its members in practice. COS is recognized as the authority on eye care in Canada and has set vision standards used by the federal government for automobile drivers, pilots, fire fighters, police officers and the Canadian Coast Guard.

www.eyesite.ca >

THE CANADIAN ASSOCIATION OF OPTOMETRISTS (CAO)
The Canadian Association of Optometrists is a national organization of 3,000 optometrists. Its mission is to represent the profession of optometry, advance the quality, availability of eye, vision, and related health care, enhance and promote the independent and ethical decision-making of its members, and assist doctors of optometry in practicing successfully in accordance with the highest standards of patient care.

www.opto.ca >

THE INTERNATIONAL FEDERATION ON AGEING (IFA)
The International Federation on Ageing (IFA) is a private, non-profit organization, linking approximately 151 associations that represent or serve older persons at the grassroots level in some 54 nations around the world. Through IFA, individuals and organizations that work with older persons or on their behalf can exchange information and ideas, communicate common concerns, share practical applications, and learn from each other's experiences. IFA is committed to the dignity, independence and empowerment of older persons.

www.ifa-fiv.org >

L'ASSOCIATION QUÉBÉCOISE DE LA DÉGÉNÉRESCENCE MACULAIRE (AQDM)

L'AQDM est là pour vous informer sur cette maladie oculaire qui affecte un grand nombre de personnes de plus de 50 ans et même des personnes plus jeunes. Depuis sa fondation, l'AQDM a pour mission d'encourager l'autonomie et de faciliter l'entraide des personnes atteintes de dégénérescence maculaire; de diriger les personnes atteintes de dégénérescence maculaire vers les ressources médicales, technologiques et socio-culturelles existantes; et, de les informer de la prévention possible, des traitements et des recherches menées à travers le monde et de sensibiliser les professionnels de la santé ainsi que le grand public à cette maladie.

www.degenerescencemaculaire.ca >

THE NATIONAL COALITION FOR VISION HEALTH
The National Coalition for Vision Health is a non-profit coalition of Canadian organizations and service providers of the vision-care industry, research, education, rehabilitation and consumers. The Coalition provides leadership for the improvement of vision health and eye care through research and public awareness, and by supporting public and professional education and information, vision loss prevention initiatives and vision health.

www.visionhealth.ca >

THE FOUNDATION FIGHTING BLINDNESS (FFB)
The Foundation Fighting Blindness (FFB) is the leading eye research foundation in Canada. The FFB is an innovative and committed fundraiser, quality provider of research information and a dynamic partner in a network of like-minded organizations. The FFB supports and promotes research directed to finding the causes, treatments and ultimately the cures for retinitis pigmentosa, macular degeneration and related retinal diseases.

www.ffb.ca >

NOVARTIS OPHTHALMICS AG

With worldwide headquarters in Basel, Switzerland, the Novartis Ophthalmics Business Unit is a global leader in research, development and manufacturing of leading ophthalmic pharmaceuticals that assist in the treatment of Age-Related Macular Degeneration, eye inflammation, glaucoma, ocular allergies and other diseases and disorders of the eye. Novartis Ophthalmics products are available in more than 110 different countries. The North American headquarters is based in East Hanover, New Jersey. Novartis Ophthalmics products are made in Switzerland , France and Canada.

www.novartisophthalmics.ca >

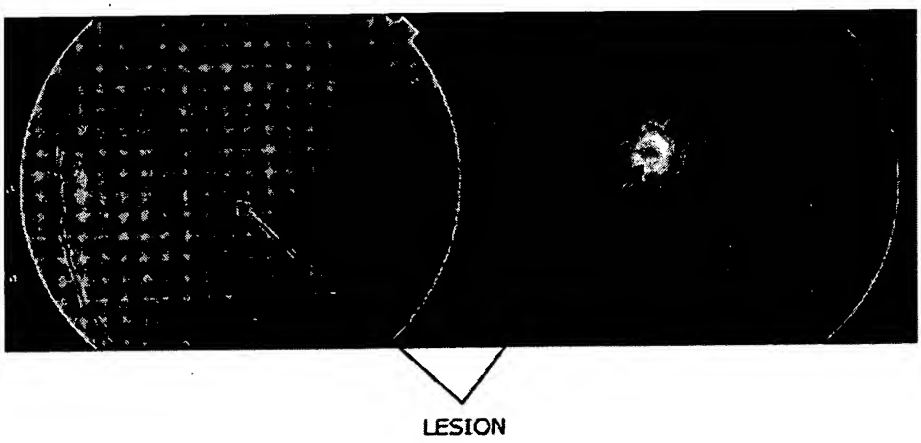
www.amdcanada.com

CLASSIC CNV

Classic CNV refers to a well-defined area of new blood vessel growth in the macula. It may be detected on clinical

examination or through retinal photography and intravenous fluorescein angiography (a specialized series of photographs of the retina) (Figure 1). Classic CNV is typically associated with more severe and rapid vision loss than other types of CNV, such as occult CNV.

Fig. 1: Fundus Photograph with Classic Wet AMD (CNV) [left], and its Corresponding Fluorescein Angiogram [right]

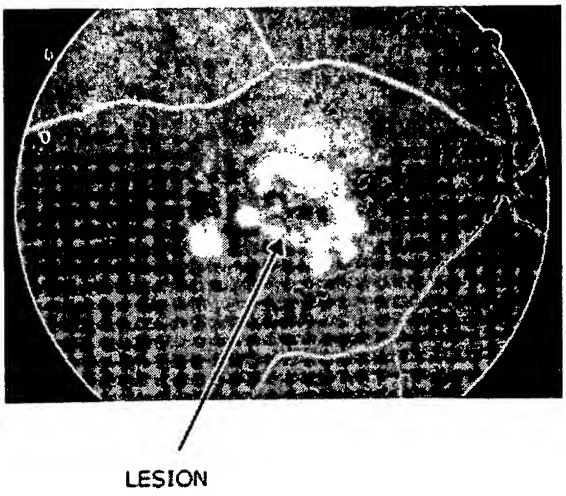


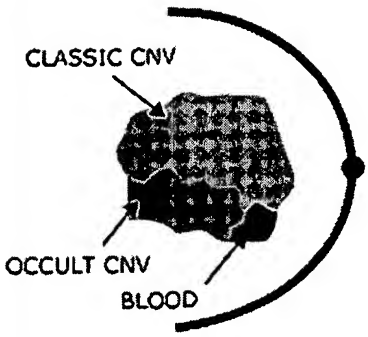
Diagnosis and treatment would be easier if all lesions were either distinctly classic or occult, but like much about this disease, it is not that simple. Lesions are often made up of varying combinations of classic and occult components, making identification and treatment that much more of a challenge.

Predominantly Classic CNV

A predominantly classic CNV lesion has a mix of both classic and occult CNV characteristics. This type of lesion is called predominantly classic because the classic component makes up more than 50% of the entire lesion (Figure 2).

Fig. 2: Fluorescein Angiogram with Predominantly Classic Lesion [left], and Schematic of Lesion Component Break-down [right]





The diagram accompanying the fluorescein angiogram shows the classic CNV to be the predominant component of the entire lesion.

Minimally Classic CNV

A minimally classic CNV lesion is identified when the classic component occupies less than 50% of the total lesion area and the occult component is more than 50% of the lesion.

In this image (figure 3), the classic CNV is surrounded by a much larger area of occult CNV.

Fig. 3: Fluorescein Angiogram with Minimally Classic Lesion [left], and Schematic of Lesion Component Break-down [right]